K021313

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

In Accordance with SMDA of 1990

Search Evolution Total Knee System

April 1, 2001

COMPANY: Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034

CONTACT: Joyce Kilroy
800-258-1946 (phone)
610-791-6882 (fax)
joyce.kilroy@aesculap.com (email)

TRADE NAME: Search Evolution

COMMON NAME: Search Evolution Total Knee System

DEVICE CLASS: Class II

PRODUCT CODE: 87 JWH

CLASSIFICATION: 888.3560 - Prosthesis, Knee, Patellofemortibial Semi-constrained, Cemented, polymer/metal/polymer

REVIEW PANEL: Orthopedics

INDICATIONS FOR USE

The Search Evolution Total Knee System is indicated for use in reconstruction of the diseased knee joint caused by osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, the need to revise failed arthroplasties or osteotomies where pain, deformity or dysfunction persist, and for patients suffering from correctable valgus or varus deformity and moderate flexion contracture.

For Posterior Stabilized (PS) Components:

Absent or non-functioning posterior cruciate ligament and severe anteroposterior instability of the knee joint.

The Search Evolution Knee is designed for use with bone cement.

DEVICE DESCRIPTION

The cemented Search Evolution Knee System is available with two femoral designs, the Posterior Stabilizing (PC) and the Ligament, Cruciate (LC) which retains the ligament (PCL) during implantation. Both designs of the femoral components, and interchangeable tibial plateaus (trays) are manufactured from CoCrMo. The tibial "gliding surfaces" (inserts) and patellas are manufactured from UHMWPE.

PERFORMANCE DATA

All required testing per "Draft Guidance for the Preparation of Premarket Notifications (510(k)s) for Cemented, Semi-constrained Total Knee Prostheses" were completed. Biomechanical testing results demonstrate the Search Evolution Knee System is substantially equivalent to other knee systems currently on the market.

SUBSTANTIAL EQUIVALENCE

Aesculap®, Inc. believes that the Search Evolution Total Knee System is substantially equivalent to:

- Scorpio Posteriorly Stabilized Knee System (K962152)
- Scorpio Total Stabilizer Total Knee System (K994128)
- Scorpio Posterior Cruciate Retaining Knee System (K974556)
- Gem Knee System (K994214)
- Gem Posterior Stabilized Total Knee System (K010101)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 2 2002

Ms. Joyce Kilroy
Director, Regulatory Affairs and Quality Assurance
Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K021313
Trade/Device Name: Search Evolution Total Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: April 23, 2002
Received: April 25, 2002

Dear Ms. Kilroy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Milhous

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

B. INDICATIONS FOR USE STATEMENT

510(k) Number: K021313

Device Name: **Search Evolution Total Knee System**

Indication for Use:

The Search Evolution Total Knee System is indicated for use in reconstruction of the diseased knee joint caused by osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, the need to revise failed arthroplasties or osteotomies where pain, deformity or dysfunction persist, and for patients suffering from correctable valgus or varus deformity and moderate flexion contracture.

For Posterior Stabilized (PS) components:
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The Search Evolution Knee is designed to for use with bone cement.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021313

Prescription Use _____ or Over-the-Counter Use _____

(per 21 CFR 801.109)